FILED
2024 Dec-17 PM 01:50
U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
MIDDLE DIVISION

CHARITY WALTERS,	}	
	}	
Plaintiff,	}	
	}	
v.	}	**Case No.: 4:24-cv-01328-RDP**
	}	
BOSTON SCIENTIFIC CORP.,	}	
	}	
Defendant.	}	

MEMORANDUM OPINION

This case is before the court on Defendant Boston Scientific Corporation's ("BSC") Motion to Dismiss. (Doc. # 2). The Motion has been fully briefed (Docs. # 2, 6, 7). After careful consideration, the court concludes that BSC's Motion (Doc. # 2) is due to be granted.

I. Background and Procedural History

Plaintiff Charity Walters ("Walters"), as personal representative of the estate of Naomi Joy Lee ("Lee"), has filed suit against Defendant BSC, asserting claims of products liability, negligence, breach of warranty, and wrongful death. (Doc. # 1-1).

In her complaint, Walters alleges that on or about March 22, 2022, Lee was prescribed and began using a defibrillator that was manufactured by BSC. (*Id.* ¶ 5). According to Walters, the defibrillator was model number 8219[1] and was intended to "monitor Lee's heart rhythm and deliver an electric shock if necessary to restore normal heart rhythm." (*Id.* ¶ 6). However, Walters alleges that on September 7, 2024, the defibrillator failed to operate as intended. (*Id.* ¶ 7). Although Plaintiff alleges that Lee suffered a cardiac event and died on September 7, 2024 (Doc. # 1-1 ¶ 7), this

[1] In its motion to dismiss, BSC contends that the defibrillator is an "EMBLEM MRI S-ICD® product bearing the identification number A219/150459." (Doc. # 2 at 1). It also describes the defibrillator as a "'Class III' subcutaneous implantable defibrillator system that provides defibrillation therapy in patients who are at risk for sudden cardiac arrest." (*Id.* at 1-2).

action was filed the day prior on September 6, 2024. (Doc. # 1-1). BSC alleges in its Notice of Removal that "[u]pon information and belief, Lee actually died on September 27, 2022." (Doc. # 1 at 2 n.1). For these reasons, the court assumes that the alleged cardiac event and Lee's death actually occurred on September 27, 2022. On that day, Lee experienced a "cardiac event requiring intervention," but the defibrillator failed to send a signal to the monitoring clinic, "as it was designed and intended to do." (*Id.*). Walters further alleges that "[a]s a result of the defibrillator's failure, Lee did not receive timely medical intervention." (*Id.* ¶ 8). Additionally, Walters alleges that the defibrillator caused burns to Lee's body (*id.* ¶ 9) and that "[a]s a direct and proximate result of the defibrillator's failure, Lee suffered severe injuries and ultimately died on September [27, 2022]." (*Id.* ¶ 10).

This action was originally filed in the Circuit Court of St. Clair County, Alabama. (Doc. # 1-1). BSC timely removed the case on September 30, 2024. (Doc. # 1).

II. Standard of Review

The Federal Rules of Civil Procedure require that a complaint provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, the complaint must include enough facts "to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Pleadings that contain nothing more than "a formulaic recitation of the elements of a cause of action" do not meet Rule 8 standards, nor do pleadings suffice that are based merely upon "labels and conclusions" or "naked assertion[s]" without supporting factual allegations. *Id.* at 555, 557. In deciding a Rule 12(b)(6) motion to dismiss, courts view the allegations in the complaint in the light most favorable to the non-moving party. *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007).

To survive a motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable

for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although "[t]he plausibility standard is not akin to a 'probability requirement,'" the "complaint must demonstrate 'more than a sheer possibility that a defendant has acted unlawfully.'" *Id*. A plausible claim for relief requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" to support the claim. *Twombly*, 550 U.S. at 556.

In considering a motion to dismiss, a court should "1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, 'assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" *Kivisto v. Miller, Canfield, Paddock & Stone, PLC*, 413 F. App'x 136, 138 (11th Cir. 2011) (quoting *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir. 2010)). That task is context specific and, to survive the motion, the allegations must permit the court based on its "judicial experience and common sense . . . to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679. If the court determines that all the well-pleaded facts, accepted as true, do not state a claim that is plausible, the claims are due to be dismissed. *Twombly*, 550 U.S. at 570.

III. Analysis

Walters asserts four claims against BSC: strict products liability, negligence, breach of warranty, and wrongful death. (Doc. # 1-1). In its Motion to Dismiss, BSC argues that none of Walters's allegations state a claim upon which relief can be granted because they are expressly preempted by federal law. (Doc. # 2). Below, the court considers BSC's preemption argument and ultimately concludes that Walters's claims are in fact preempted.

Preemption finds its authority in the Supremacy Clause of the United States Constitution, which provides: "the Laws of the United States . . . shall be the supreme Law of the Land." U.S.

Const. art. VI, cl. 2. Thus, "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

Congress passed the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug, and Cosmetic Act ("FDCA"), giving the FDA regulatory authority over medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (citing 21 U.S.C. § 360(c)). Under this authority, the FDA classifies medical devices into three categories (depending on the level of risk presented) and then approves the medical devices for entry into the market by evaluating each device's effectiveness and safety – known as premarket approval ("PMA"). *Mink v. Smith & Nephew*, 860 F.3d 1319, 1325 (11th Cir. 2017).

The approval process for medical devices (particularly Class III devices, which is the highest category of risk) is rigorous and requires the FDA to spend (on average) over 1,200 hours reviewing each application. *Riegel*, 552 U.S. at 317-18 (internal citations omitted). Unsurprisingly then, an application includes large amounts of data on the effectiveness and safety of the device under review, descriptions of facilities, manufacturing specifications, processes for device production, and proposed product labeling. *Id.*; 21 U.S.C. § 360e(c). Based on this data, and only after weighing the health benefits of the device's use against the risks of injury associated with the device, and only after concluding that "there is a reasonable assurance" of the device's "safety and effectiveness," may the FDA grant PMA. *Riegel*, 552 U.S. at 318-19 (citing 21 U.S.C. §§ 360c, 360e(d)). After the FDA grants PMA, the applicant may not make any changes to "design specifications, manufacturing processes, labeling, or any other attribute" that would "affect [its] safety or effectiveness" without first obtaining FDA approval. *Id.* at 319; *Mink*, 860 F.3d at 1325 (citing 21 U.S.C. § 360e(d)(5)(A)(i)).

The court begins its analysis by examining the scope of preemption. Again, a Class III device is subject to "rigorous" scrutiny before the FDA approves it for commercial use. *Riegel*, 552 U.S. at 312, 316. Congress, recognizing that a manufacturer cannot deviate from requirements in the PMA and MDA, enacted an express preemption provision that applies to Class III devices after their approval:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is *different from, or in addition to,* any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Preemption goes beyond state regulatory enforcement and includes state common law or statutory liability. The reason for preempting state-law claims is simple: if a state imposes liability on a manufacturer for producing a medical device in a manner different from what is required under the device's PMA (*i.e.*, requiring a manufacturer to meet additional requirements), then that could upset the FDA's "cost-benefit analysis" that a device, approved only after weighing the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use," provides a "reasonable assurance" of "safety and effectiveness." *Riegel*, 552 U.S. at 318-19, 325.

However, this express preemption provision does not preempt state-law claims "premised on a violation of the FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 312. Unsurprisingly, these state-law claims are commonly referred to as "parallel claims." *Mink*, 860 F.3d at 1325-26 (internal citations omitted). When analyzing a claim for express preemption, the issue is whether a plaintiff's theories of liability and the facts supporting his or her cause of action, if enforced, would hold a defendant liable for violating

requirements that are beyond the FDA's. *See Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713, at *3 (N.D. Tex. Aug. 13, 2008). Parallel claims may be based on *any* requirement, including device-specific requirements in the PMA and the generally-applicable Good Manufacturing Practices ("GMP"). *Mink*, 860 F.3d at 1331.

There is also an implied preemption provision stating that "all such proceedings for the enforcement, or to restrain violations, of this chapter *shall be by and in the name of* the United States." 21 U.S.C. § 337(a) (emphasis added); *Mink*, 552 U.S. at 1327. Implied preemption requires that the "MDA [is] . . . enforced exclusively by the Federal Government." 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (citing 21 U.S.C. § 337(a)). Thus, private litigants are not "authorized to file suit for noncompliance with the medical device provisions." *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009) (quoting *Buckman*, 531 U.S. at 349 n.4), *aff'd*, 623 F.3d 1200, 1205 (8th Cir. 2010). In other words, private litigants cannot "seek to privately enforce a duty owed to the FDA." *Mink*, 860 F.3d at 1320.

These two preemption provisions, when considered together, leave only a narrow gap for a private litigant to bring a state-law claim related to medical devices. The Eleventh Circuit has defined this "narrow gap" as follows:

> To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption). Putting these ideas into practice, . . . a plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' *and* so 'long as she can show that she was harmed by a violation of applicable federal law.'

Mink, 552 U.S. at 1327 (emphasis added) (internal citations omitted) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

Not only must the claim be premised on a duty equivalent to one required by the FDA and cognizable under state law, but the claim must also be connected to the alleged injury. *Kubicki ex rel. v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 172 (D.D.C. 2018); *see id.* at 1331 (citing *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011)).

Once a defendant invokes preemption under the MDA, the burden falls on the plaintiff to show that her claims are not preempted. *Kubicki*, 293 F. Supp. 3d at 172. This is, by necessity, a high burden. A plaintiff must "set forth [evidence] pointing to *specific* PMA requirements that have been violated" and that those violations caused the plaintiff's injury. *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (emphasis added) (internal citations omitted); *Godelia*, 881 F.3d at 1319-20. In other words, if a plaintiff simply claims that a defendant violated a federal regulation without identifying (1) the specific facts showing *how* a defendant violated either a PMA specification or a specific GMP and (2) the specific facts showing that the violation caused the injury at issue, then that plaintiff fails to adequately assert a parallel claim. *Wolicki-Gables*, 634 F.3d at 1301 (internal citations omitted).

Here, Plaintiff has not met her burden to establish that her claims are premised on binding federal requirements. Moreover, Plaintiff has also not shown that Defendant's product caused Lee's injuries. *Kubicki*, 293 F. Supp. 3d at 172; *Wolicki-Gables*, 634 F.3d at 1301.

There is a two-step inquiry for determining whether a claim is parallel or expressly preempted:

> First, a court must determine whether the Federal Government has established requirements applicable to the device. If so, [second] the court must then determine whether the plaintiff's common-law claims are based upon state law requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to the safety and effectiveness.

Mink, 552 U.S. at 1326. BSC argues that the first prong is satisfied because "the EMBLEM MRI S-ICD® is a Class III medical device that received FDA approval for commercial distribution

through the PMA process, resulting in a finding that the EMBLEM MRI S-ICD® is safe and effective." (Doc. # 2 at 11) (*see also id.* (citing Original PMA Approval Order Re: P110042 (Sept. 28, 2012)). Plaintiff does not contest this point. As such, after reviewing BSC's cited authority, the court takes judicial notice of the fact that EMBLEM MRI S-ICD® was approved for commercial distribution by the FDA through the PMA process.

Considering the second prong, the court finds that Walters's state law claims are premised on state-law duties different from those imposed by the PMA Approval Order and relate to the safety and effectiveness of the defibrillator. Therefore, they are expressly preempted.

In her Complaint, Walters does not cite to (or even mention) any relevant federal requirements that BSC violated in the design, manufacture, or labeling of the defibrillator. Walters asserts a claim for strict products liability, alleging only that "[t]he defibrillator was defective and unreasonably dangerous when it left Defendant's control." (Doc. # 1-1 ¶ 12). Similarly, she asserts a negligence claim, alleging that BSC "owed a duty of care to Naomi Joy Lee to design, manufacture, and sell a safe and effective defibrillator" (*id.* ¶ 14) and that BSC "breached this duty by failing to provide a product that performed as expected and relied upon for maintaining proper heart rhythm." (*Id.* ¶ 15). And, pursuant to her claim for breach of warranty, Walters alleges that BSC "expressly and impliedly warranted that the defibrillator was safe and fit for its intended purpose" (*id.* ¶ 18) and "[t]he defibrillator was not safe or fit for its intended purpose, breaching these warranties." (*Id.* ¶ 19). Finally, in her claim for wrongful death, Walters alleges that "[a]s a direct and proximate result of Defendant's wrongful conduct as described above, Naomi Joy Lee died." (*Id.* ¶ 22). Again, there is no mention of *any* federal requirement that was allegedly violated by BSC.

Additionally, in response to BSC's motion to dismiss, Walters does not address BSC's preemption argument. Nor does she cite to any federal regulations that BSC allegedly violated. Walters's response only includes this bare argument: "Plaintiff has sufficiently pled necessary elements of strict products liability, negligence, breach of warranty, and wrongful death claims." (Doc. # 6 at 1).

For all of these reasons, Walters has not met her burden to plead specific violations of federal regulations. *Wolicki-Gables*, 634 F.3d at 1301-02 (holding that in order to survive § 360k(a)'s preemptive effect, "[a] plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue") (internal quotation makes omitted). Thus, Walters's claims are preempted under § 360k(a) and they fail as a matter of law.

IV. Conclusion

For the reasons explained above, BSC's Motion (Doc. # 2) is due to be granted. A separate order in accordance with this memorandum opinion will be entered contemporaneously.

DONE and **ORDERED** this December 17, 2024.

R. DAVID PROCTOR
CHIEF U.S. DISTRICT JUDGE